IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and EDWARD LIFESCIENCES, LLC, Plaintiffs, v. COREVALVE, INC. and MEDTRONIC COREVALVE, LLC, Defendants.	)	C.A. No. 08-091-GMS [redacted] REDACTED - PUBLIC VERSION

DECLARATION OF RHONDA ROBB

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Dated: June 24, 2013

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EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES, LLC, Plaintiffs, v. COREVALVE, INC. and MEDTRONIC COREVALVE, LLC, Defendants. AND RELATED COUNTERCLAIMS.	Case No. C.A. No. 08-091 (GMS)

DECLARATION OF RHONDA ROBB

I, Rhonda Robb, declare under penalty of perjury that:

1. I currently hold the title of Vice President and General Manager, Catheter-Based Therapies at Medtronic, Inc. Among my responsibilities is the development of Medtronic's global business for the Medtronic CoreValve transcatheter aortic valve replacement (TAVR) product. I have held this position since 2009. In this role, I regularly visit and speak with physicians around the world who are using the CoreValve device, as well as many physicians who use or are familiar with both Edwards' Sapien 9000TFX and the Sapien XT device recently introduced in Europe but not approved in the US. Except where indicated, I have personal knowledge of, and could testify under oath to the matters set forth below if called upon to do so.

2. I took over responsibility for the CoreValve program in July 2009, shortly after Medtronic's acquisition of CoreValve in April 2009. At that time, CoreValve had obtained regulatory approval to market its device in Europe (CE Mark approval) and certain other countries around the world, but had not obtained FDA approval to market the device in the United States.

3. In Europe, CoreValve's device was the first transcatheter aortic heart valve to receive CE Mark approval, and so was the first to market there. Edwards came to market in Europe with its Sapien 9000TFX soon thereafter. There has been relatively healthy competition in Europe between Edwards and Medtronic in the TAVR field. The current market share for TAVR in Europe between Medtronic CoreValve and Edwards is [redacted] Global share shifted significantly favoring Edwards with the introduction of the Sapien 9000TFX into the United States.

4. I understand from a number of experienced physicians that there are some very important differences between the CoreValve and Sapien device platforms. These differences are well understood by physicians. For example, attached hereto as Exhibit A is a true and correct copy of slides presented by Dr. Raj Makkar, a principal site investigator for Sapien

clinical trials. Among the design differences that are readily apparent and that impact the willingness of a physician to try one product over the other are:

i) CoreValve is a self-expanding nitinol frame, whereas all Sapien devices are made using a balloon expandable frame. This difference has implications for the necessary steps to complete a procedure as well as with patient selection. Procedurally, many physicians prefer the simplicity of a self-expanding design that allows for slow deployment without the requirement for fast ventricular pacing. The CoreValve self-expanding frame has the ability to conform to different anatomies and is seen as a very adaptable platform providing flexibility in patient selection and treatment strategies.

ii) In part because of its self-expanding design, the CoreValve device can be maneuvered into place gradually, while allowing for partial repositioning as the valve is being released. This slow and controlled deployment provides added flexibility to ensure proper placement of the device. I have witnessed physicians taking advantage of this ability during procedures, and I find that most physicians are very receptive to this capability and appear to value it highly. Procedural complications with the CoreValve device are very low; according to the ADVANCE trial where there were no annular ruptures, 0.1% conversion to open AVR, and 0.1% coronary compromised. With CoreValve, physicians believe there is less trauma to the annulus and aorta because of the self-expanding design.

iii) Most importantly, however, is the patient population that can be treated. CoreValve provides the smallest delivery catheter (6mm in diameter) that is used for all CoreValve devices, across the entire valve size matrix. This is important to accommodate patient vessel size as small as 6mm in diameter and reduce trauma to the vessels as the device is being advanced into place. This single-size, small delivery catheter contrasts with the larger delivery catheters of various models and sizes of Sapien devices. None of the Sapien 9000TFX devices uses a 6 mm delivery catheter, and of the Sapien XT devices, only its smallest device (the Sapien XT 23 mm device) uses a 6 mm catheter. The entire Sapien 9000TFX platform and all but the smallest Sapien XT valves require larger delivery catheter profiles (up to 8 mm). As a

result of this disparity, many doctors will not treat patients with particularly narrow, tortuous or calcified blood vessels using a Sapien device. In addition, CoreValve has a wider range of device sizes that can treat patients with an aortic annulus from 18mm to 29 mm in diameter. Sapien is limited to annulus size of 25 mm or less with the current commercially released devices in the US. Outside of the United States, the largest Sapien XT device can accommodate up to a 27mm annulus per the IFU.

iv) Finally, CoreValve access site versatility is an important distinction. CoreValve has commercial approval (CE mark) for subclavian and direct aortic access routes in addition to transfemoral access. These 'alternate access' routes are also under study in the US IDE and today constitute [redacted] Access route choice with the same valves/delivery catheters is an important attribute for patient selection flexibility.

5. [redacted] The Sapien device in the US is available in transfemoral and transapical routes. Other access routes in the US are not commercially available and are currently under study.

6. Because of the wider patient population that the CoreValve device can treat, many institutions who have both technologies available, provide feedback that they preferentially select a CoreValve device. In addition, institutions exclusively using a Sapien device (e.g. Sapien clinical and commercial sites), will frequently transfer patients to another institution that can use a CoreValve device because the patient is not suitable for a Sapien procedure.

7. In Europe, because two different devices are available, I strongly believe that the range of hospitals and physicians using TAVR of one variety or another is much broader than if only one product were on the market. Each product appeals to its own type of physician, who

from past experience or otherwise, may be more comfortable with the features and behavior of one type of product as opposed to the other for a given practice or patient. Both companies have effectively developed clinical evidence, educated physicians and built awareness for the therapy, greatly increasing the acceptance and adoption rate of transcatheter valves. Because the entire field of TAVR is better developed thanks to the presence of two different devices, there are more, and more productive, discussions at conferences about TAVR, leading to better education of physicians, and therefore more widespread adoption of the devices generally.

8. I understand Edwards has claimed that CoreValve has caused "price erosion" as to the Sapien devices. While I cannot speak to the factors that Edwards considers when setting its price for Sapien platform, it is my understanding that when Edwards sells a Sapien device it is as part of a "kit" of equipment needed for the procedure, including the valve, delivery system, crimper, balloon pre-dilation catheter, dilator kit and introducer sheaths. The CoreValve system consists of the valve, valve loader and delivery system. Hospitals need to separately purchase other equipment that is used in the TAVR procedure when using the CoreValve device. There are important distinctions between the systems (*e.g.,* products included) that must be considered when comparing prices. In addition, hospital purchase volumes and contractual commitments also may account for price differences and changes over time (*e.g.,* accounts that purchase more CoreValve volumes typically have better pricing).

9. Medtronic is currently conducting a clinical trial in the US and working with the FDA to seek commercial approval of the device pursuant to an FDA-approved Investigational Device Exemption (or IDE). All product distributed in the United States must comply with the IDE and be accounted for to the FDA. Pursuant to the IDE, Medtronic (just like Edwards did earlier) is entitled to recoup some of its costs of providing these devices to institutions participating in the FDA-approved IDE procedures. But that compensation is not a commercial sale.

10. Since late 2011, the Sapien 9000TFX has been the only TAVR device commercially available in the US. Since CoreValve is not expected to receive FDA approval

[redacted]

11. But again, for some of the same reasons discussed above regarding the differentiation between the products, and for the reasons already observed in Europe, most institutions in the United States are seeking an alternative to Sapien, even if their only possible use of CoreValve is for clinical trials. We understand this to be the case because Sapien cannot serve the entire patient population that would benefit from TAVR given the current indications. It is Medtronic's intention to start training existing US TAVR sites and other sites that meet CMS criteria at the time of CoreValve commercial approval. We believe that CoreValve brings a very important therapeutic choice to US heart teams/TAVR institutions to treat a broader patient population with aortic stenosis who meet the indications for the device.

12. From my familiarity with Edwards' public statements about its upcoming product development, I am aware that Edwards hopes that its newer Sapien XT device will allow Edwards to serve a broader range of patients than its current Sapien 9000TFX product. It should be noted, however, that according to statements at Edwards' December 4, 2012 analyst meeting, Sapien XT is not expected to receive FDA approval until mid to late 2014, and then only for "Inoperable" patients. It is estimated that Sapien XT will not receive approval for it's "Operable" cohort, which includes "high risk" patients, until late 2016/early 2017, whereas

[redacted]

[redacted] During this period before Sapien XT receives approval, patients in the "high risk" category that are not suited to treatment with the Sapien 9000TFX will have no TAVR device available to them if the CoreValve device were enjoined in the United States.

13. There have been several other entrants to the TAVR field recently. Direct Flow Medical, Inc. received CE Mark approval for its Transcatheter Aortic Heart Valve System in January 2013, and just recently received FDA approval for its feasibility IDE and announced that it will soon begin studies in the United States. Attached as Exhibit B is a true and correct copy of a press release announcing this development, from http://www.onlinetmd.com/direct-flow-medical-ide-approval-052013.aspx. Also, St. Jude Medical received CE Mark approval for its Portico Transcatheter Aortic Heart Valve in November 2012; and has communicated that they expect to have the Portico US IDE study approved to start by mid-2013. US Primary Investigators have been named and feedback from the Medtronic US field team indicates that US site selection is underway, and St. Jude is primarily targeting CoreValve sites. According to its April 25, 2013 earnings call, Boston Scientific has announced that it expects CE Mark approval for its Lotus Valve by Q4 2013 and that they are starting discussions with the FDA on their IDE trial. JenaValve and Symetis have also announced products in various stages of clinical trials or rollout around the world.

I declare under penalty of perjury that the foregoing is true and correct. Executed on June 20, 2013, at Mounds View, MN.

Rhonda S Rose

EXHIBIT A
REDACTED ENTIRELY

EXHIBIT B

Direct Flow Medical Receives IDE Approval

INDUSTRY NEWS, CARDIOVASCULAR, DESIGN, FDA, COMPONENTS

Investigational Device Exemption allows start of the SALUS feasibility trial of the Direct Flow Medical Transcatheter aortic heart valve system.

Manufacturing Group

MAY 20, 2013

Direct Flow Medical Inc. officials announce that it has received approval from the United States Food and Drug Administration (FDA) for an Investigational Device Exemption (IDE) to begin the SALUS feasibility trial of the Direct Flow Medical Transcatheter Aortic Heart Valve System. The device encompasses a distinctive transcatheter aortic heart valve with a metal-free frame and flexible, low-profile delivery system that virtually eliminates aortic regurgitation. It is designed to improve the long-term survivability of patients by resolving the clinical issues associated with current commercial valves.

Post-procedural aortic regurgitation following transcatheter aortic heart valve replacement (TAVR) has been shown to be a predictor of long-term mortality[1]. The Direct Flow Medical Transcatheter Aortic Valve System is designed to address this clinical concern by enabling in-situ hemodynamic assessment after the valve is fully deployed in the native valve annulus, as well as limitless repositioning with full distal, proximal, and planar control, or retrieval, if required. The system avoids rapid pacing of the heart during deployment, and post-dilatation following placement, minimizing the risk of hemodynamic stress for patients.

"Paravalvular leak leading to aortic regurgitation continues to be a clinical complication of TAVR and has been correlated to long term unfavorable outcomes," says Murat Tuczu, MD, Professor of Medicine, Cleveland Clinic, Cleveland, Ohio, and co-principal investigator of the trial. "The Direct Flow Medical system has shown the ability to virtually eliminate this problem, and I look forward to studying this promising new treatment in this U.S. feasibility trial."

With receipt of IDE approval, Direct Flow Medical plans to commence its U.S. clinical study evaluating the use of the Direct Flow Medical Transcatheter Aortic Heart Valve System. The system includes a distinctive heart valve with a metal-free frame that will be delivered transfemorally via a flexible, 18 French delivery system. The SALUS Trial is a 30-patient feasibility trial that will be conducted at up to six U.S. clinical sites, led by co-principal investigators Dr. Tuczu and Vinod Thourani, MD, Associate Professor of Surgery, Division of Cardiothoracic Surgery, Department of Surgery, Emory University School of Medicine and the Emory Clinic.

"It is a major milestone for our company to bring our rigorous clinical research to the U.S. in order to improve outcomes for patients," states, Bernard Lyons, CEO, Direct Flow Medical. "Our device has shown the ability to achieve excellent outcomes while minimizing the risk of aortic regurgitation in our European trials, and we expect to demonstrate the same in our U.S. study."

Six-month results from the company's DISCOVER CE Mark Trial presented at the American College of Cardiology (ACC) 2013 Annual Meeting, which studied the Direct Flow Medical system, demonstrated excellent survivability, sustained hemodynamic improvements and few adverse events, with minimal occurrence of aortic regurgitation[2].

The Direct Flow Medical system received the CE Mark in January 2013 and is currently available commercially in Europe.

About The Direct Flow Medical System

The benefits of the Direct Flow Medical Transcatheter Aortic Valve System are enabled by its design, which features a distinctive, metal-free frame. Rather than a metal stent, the Direct Flow Medical System incorporates a polymer frame, which is expanded using pressurized saline and contrast for placement, assessment and repositioning. The saline/contrast solution is easily exchanged for a quick-curing polymer that solidifies and secures the valve in place once optimal positioning is reached. The unique double-ring design of the valve creates a tight seal around the annulus. The system is fully repositionable and retrievable up until polymer exchange. The metal-free design enables a low-profile (18 French), fully sheathed delivery system for all valve sizes that minimizes vascular complications and improves hemodynamic outcomes.

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1 Kodali S, Williams M Smith C, et al. Two-year outcomes after transcatheter or surgical aortic-valve replacement. N Engl J Med 2012;366(18):1686-1695.

2 Colombo A, De Marco F, Fadajet J, et al. The DISCOVER CE trial: 6-month outcomes of the Direct Flow Medical transcatheter aortic valve. JACC 2013;61 (10):E1983

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POST COMMENT

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CERTIFICATE OF SERVICE

I, David M. Fry, hereby certify that on June 24, 2013, I caused a true and correct copy of the foregoing document to be served on the following counsel in the manner indicated:

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